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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Christophe P.G. Gerald, et al.  
Serial No. : 09/538,036 Group Art Unit: 1646  
Filed : March 29, 2000 Examiner: J.F. Murphy  
For : DNA ENCODING MAMMALIAN NEUROPEPTIDE FF  
(NPFF) RECEPTORS AND USES THEREOF

1185 Avenue of the Americas  
New York, New York 10036  
January 23, 2002

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**COMMUNICATION IN RESPONSE TO OCTOBER 23, 2001 OFFICE ACTION**

This Communication is submitted in response to the Office Action issued October 23, 2001 by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the October 23, 2001 Office Action is due January 23, 2002. Accordingly, this Communication is being timely filed.

**Rejection Under 35 U.S.C. §112, First Paragraph**

On page 2 of the October 23, 2001 Office Action, the Examiner rejected claims 218-235 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner stated that the deposit of the biological material is considered necessary for the enablement of the current invention, and that elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification.

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The Examiner alleged that the specification is not fully compliant with all the provisions for maintenance and availability of the deposited material.

The Examiner stated that if a deposit is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of Patent Procedure, and applicants, their assignee or their agent needs to provide a declaration containing the following:

- i) a statement all restriction on the availability to the public of the deposited material so deposited will be irrevocably removed upon the granting of a patent;
- ii) a statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. §122;
- iii) a statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer; and
- iv) a statement by declarant that all statements are true and that all statements were made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title

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18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any issuing thereon.

In response, applicants point out that the plasmids have been deposited under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of Patent Procedure. Applicants attach hereto as **Exhibit A**, a copy of the ATCC Deposit Receipt for plasmids pWE15-hNPFF1 and pEXJ-rNPFF1 (ATCC Accession No. 203183 and ATCC Accession No. 203184, respectively) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on September 9, 1998; as **Exhibit B**, a copy of the ATCC Deposit Receipt for plasmid pcDNA3.1-hNPFF2b (ATCC Accession No. 203255) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on September 22, 1998; as **Exhibit C**, a copy of the ATCC Deposit Receipt for plasmid pcDNA3.1-hNPFF1 (ATCC Accession No. 203605) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on January 21, 1999; and as **Exhibit D**, a copy of the ATCC Deposit Receipt for plasmid pcDNA3.1-rNPFF2-f (Patent Deposit Designation No. PTA-535) indicating that the deposit was made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure on August 17, 1999.

Under the terms of the deposit, the deposited materials will be maintained for a period of at least 30 years from date of

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deposit, or for five years after the most recent request for a sample, whichever period is longer (see ATCC Deposit receipts, Exhibits A-D; 37 C.F.R. §1.806).

In addition, under the terms of the deposit, the deposited materials will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the deposited materials, and ATCC is instructed by the United States Patent and Trademark Office or the depositor to release said materials (see ATCC Deposit receipts, Exhibits A-D; 37 C.F.R. §1.808(a)(1)).

Furthermore, applicants' undersigned attorney states herewith that in accordance with 37 C.F.R. §1.808(a)(2) all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent from the subject application. Where the ATCC cannot furnish samples of the deposits for any reason, applicants shall make a replacement deposit of the material which was originally deposited.

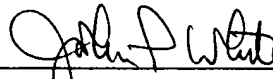
In view of the foregoing, applicants maintain that claims 218-235 comply with the requirements of 35 U.S.C. §112, first paragraph, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

If a telephone conference would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.

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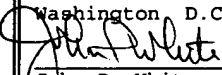
No fee is deemed necessary in connection with the filing of this Communication. However, if a fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

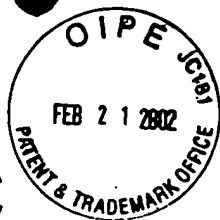


John P. White  
Registration No. 28,678  
Attorney for Applicants  
Cooper & Dunham LLP  
1185 Ave of the Americas  
New York, New York 10036  
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

 1/23/02  
John P. White Date  
Reg. No. 28,678

**ATCC**



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**BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF  
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**

**INTERNATIONAL FORM**

**RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2**

**To: (Name and Address of Depositor or Attorney)**

**Cooper & Dunham, LLP  
Attn: John P. White, Esq.  
1185 Avenue of the Americas  
New York, NY 20036**

**Deposited on Behalf of:** Synaptic Pharmaceutical Corp. (Ref. Docket 57155)

**Identification Reference by Depositor:**

**ATCC Designation**

Cosmid pWE15-hNPFF1  
Plasmid pEXJ-rNPFF1

203183  
203184

The deposits were accompanied by:      a scientific description      a proposed taxonomic description indicated above. The deposits were received September 9, 1998 by this International Depository Authority and have been accepted.

**AT YOUR REQUEST: ☒ We will inform you of requests for the strains for 30 years.**

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested September 16, 1998. On that date, the cultures were viable.

**International Depository Authority:** American Type Culture Collection, Manassas, VA 20110-2209 USA.

**Signature of person having authority to represent ATCC:**

  
Barbara M. Hailey, Administrator, Patent Depository

**Date:** September 17, 1998

cc: Mary Anne Tanner, Esq.

Applicant: Christophe P.G. Gerald et al.  
U.S. Serial No.: 09/538,036  
Filed: March 29, 2000  
**Exhibit A**

# ATCC



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Cooper & Dunham LLP  
Attn: John P. White, Esq.  
1185 Avenue of the Americas  
New York, NY 10036

**Deposited on Behalf of:** Synaptic Pharmaceutical Corporation (Ref. Docket 57155)

**Identification Reference by Depositor:**

**ATCC Designation**

Plasmid pCDNA3.1-hNPFF2b

203255

The deposit was accompanied by: \_\_\_ a scientific description \_\_\_ a proposed taxonomic description indicated above.

The deposit was received September 22, 1998 by this International Depository Authority and has been accepted.

**AT YOUR REQUEST:** X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested October 2, 1998. On that date, the culture was viable.

**International Depository Authority:** American Type Culture Collection, Manassas, VA 20110-2209 USA.

**Signature of person having authority to represent ATCC:**

Barbara M. Hailey  
Barbara M. Hailey, Administrator, Patent Depository

**Date:** October 7, 1998

**cc:** Mary Anne Tanner, Esq.

Applicant: Christophe P.G. Gerald et al.  
U.S. Serial No.: 09/538,036  
Filed: March 29, 2000  
**Exhibit B**

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Cooper & Dunham LLP  
Attn: John P. White, Esq.  
1185 Avenue of the Americas  
New York, NY 10036

Deposited on Behalf of: Synaptic Pharmaceutical Corporation (Ref. Docket 57155)

Identification Reference by Depositor:

ATCC Designation

Plasmid DNA pcDNA3.1-hNPFF1

203605

The deposit was accompanied by: \_\_\_ a scientific description \_\_\_ a proposed taxonomic description indicated above.

The deposit was received January 21, 1999 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested January 27, 1999. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

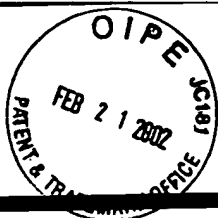
Barbara M. Hailey  
Barbara M. Hailey, Administrator, Patent Depository

Date: January 28, 1999

Applicant: Christophe P.G. Gerald et al.  
U.S. Serial No.: 09/538,036  
Filed: March 29, 2000  
**Exhibit C**



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New York, NY 10036

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Deposited on Behalf of: Synaptic Pharmaceutical Corporation

Identification Reference by Depositor:

Patent Deposit Designation

Plasmid pEXJ.T3T7-rSNORF36p (Ref. Docket 59138-A)  
Plasmid pcDNA3.1-rNPFF2-f (Ref. Docket 57155-B-PCT)

PTA-534  
PTA-535

The deposits were accompanied by: \_\_\_ a scientific description \_ a proposed taxonomic description indicated above. The deposits were received August 17, 1999 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested August 26, 1999. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey  
Barbara M. Hailey, Administrator, Patent Depository

Date: August 27, 1999

Applicant: Christophe P.G. Gerald et al.  
U.S. Serial No.: 09/538,036  
Filed: March 29, 2000  
Exhibit D